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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,016	03/12/2002	Heikki Hyoty	U 013757-2	2116

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LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,016	HYOTY ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/18/2004, 1/10/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 12-45* is/are pending in the application.

4a) Of the above claim(s) *1,12-19,21 and 31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-30 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1, 12-19, 21, 31-35 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/22/2004.

Claim Rejections - 35 USC § 112

Claims 20, 22-30, 36-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Most of the claims have been amended to require post-natal or pre-natal administration to a person in a high risk group for contracting Type I diabetes. Applicant argues that it is well-settled that, if one skilled in the art would be able to discern an appropriate dosage based on knowledge of similar compounds, this would be sufficient to satisfy the enablement provisions of 35 USC 112, first paragraph. Applicant argues that the specification teaches that the claimed dose can correspond to that which is used in the traditional Sabin-type OPV, and the specification describes a study where this dose has been used in a whole population, and Figure 1 illustrates the effectiveness of the dose on the prevalence of IDDM in the population. Figure 1 does show a small but significantly decreased incidence of IDDM in the whole population. However, the claims are drawn to preventing IDDM in an individual, and the specification does not

teach how to predict what amount (if any) is effective for an individual. In the whole-population study, the amount used was not effective for many individuals, since IDDM was not prevented in the whole population.

In addition, most of the claims now require the dose to be effective in high-risk individuals, and the data for the whole population do not show what effect is observed in the high-risk subpopulation. The publication by Graves et al documents that IDDM did develop in high-risk individuals despite routine and repeated OPV vaccination. Graves does not compare the rate of incidence in high-risk individuals untreated with OPV, but the data presented in Graves does indicate that routine immunization is not wholly effective in preventing IDDM in this subpopulation. The previous Office action presented evidence that those skilled in the IDDM art would not unquestioningly accept the assertion that vaccination is capable of preventing IDDM. Considering the nature of the invention, the lack of agreement in the art (both prior to the invention and later) regarding the relationship between virus infection and IDDM, the quantity of experimentation required, the limited guidance and the absence of working examples, it is maintained that undue experimentation would be required to establish "an amount effective to elicit a protective immune response against Type I diabetes mellitus (IDDM)" in the high-risk groups now recited.

Claim Rejections - 35 USC § 102

Claims 20, 22, 36-38, 40, 41, 43, 44 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. In the specification, it is stated that a single dose of OPV was administered to practically the whole population of Finland. This

population is large enough to include members of the high-risk groups recited in these claims. Since there was no effort to exclude subjects from high-risk groups, these subjects were necessarily selected for immunization. If the method as claimed is effective, then it was publicly used in Finland more than a decade before this patent application. Even if a prior artisan does not recognize a function of his or her process, the process can anticipate if that function was inherent.

In regard to claims 39, 42, and 45, the examiner cannot meet the burden of showing that any Finnish children in 1985 had been tested for diabetes-related antibodies; if any had, then these claims would also be unpatentable because of prior public use of the claimed method.

Claims 20, 22, 20, 22-24, 36-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the WHO Weekly Epidemiological Record (71:133-140, 1996). The reference teaches administering repeated doses of OPV to children starting at birth. The reference provides evidence that these repeated doses are routinely used in many countries, indicating administration to a very large number of children over a very large segment of the world population. The reference does not teach administering the vaccine to an IDDM high-risk subpopulation; however, the total population of children who have received the dose is so large as to guarantee that high-risk subpopulations have been included in the pool of subjects who have previously received OPV, thereby inherently anticipating the invention. Alternatively, routine administration of OPV was well known to be useful in preventing polio. This benefit was so well known that it would have been

very obvious to use the regular OPV dosage regime for any subpopulation (excluding infection-vulnerable HIV-infected and chemically immunosuppressed subpopulations), to obtain the ordinary and expected protection from polio infection. The reference does not specifically suggest administering OPV to IDDM at-risk individuals, but suggests administering OPV to virtually everyone in a population, and does not in any way teach away from administering OPV to IDDM at-risk individuals in the population. When the asserted unexpected result of IDDM prevention is weighed against the normal and expected result of polio prevention, it is concluded that the asserted unexpected result does not overcome the obviousness of using the same product by the same active steps for the purpose of obtaining the ordinary and expected benefit of immunity to polio. The invention as a whole is therefore seen as obvious, if not anticipated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/22/05

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600